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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,145	07/31/2003	Garland L. Segner	EV31008US	1829

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/632,145	Applicant(s) SEGNER ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 3-6, 10, 11, 16, 22, 23, 26-29, 31, 32, 37, 43-47 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-9, 12-15, 17-20, 24, 25, 30, 33-36, 38-41 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/632,145</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The examiner notes the abstract of the disclosure was corrected.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4.

5. Claims 1, 2, 7-9, 12-14, 17-19, 24, 25, 30, 33-35, 38-40, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo et al (5749837) in view of Ferrera et al (2004/043168).

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6. For claims 1, 24, and 48, Palermo et al discloses a elongate flexible guidewire 100 having proximal and distal regions with associated ends wherein said distal region and associated end includes a distally tapered portion (column 4 line 3). Palermo et al shows said guidewire 100 further configured with a plurality of wire strands 112,132 helically wrapped parallel to one another and disposed on tapered distal region 104 of the core. Furthermore, Palermo et al discloses a polymer tie layer 204 disposed along the wire strands (column 4 line 13) and a lubricious polymer layer 206 disposed on the tie layer (column 4 line 11) wherein said tie layer provides the only form of attachment of wire strands 112 to core 110 (column 6 line 33). For claims 2 and 25, Palermo et al discloses the polymer tie layer 204 to be disposed over the entire length of the guidewire (column 5 line 23). For claim 7, as mentioned above, the polymer tie layer provides the only form of attachment of wire strands to core (column 6 line 33). For claim 8, Palermo et al shows the plurality of wire strands 112,132 attached to core 110 by solder or adhesives (column 4 line 6 and column 5 line 40). For claims 9 and 30, Palermo et al shows in Figure 5A the guidewire core extending to the distal end of the guidewire. For claims 12, 13, 33, and 34, Palermo et al discloses the length of the guidewire is typically about 50 to 300 cm (column 4 line 6). For claims 14 and 35, Palermo et al discloses the outer diameter of the guidewire is typically about 0.010 to 0.025 inches (column 5 line 4). For claims 17 and 38, Palermo et al discloses the length of the distal wire strands to be about 25 to 35 cm (column 7 line 15). For claims 18 and 39, Palermo et al discloses the outer diameter of the distal tip to be about 0.005 to 0.020 inches (column 6 line 14). For claims 19 and 40, Palermo et al discloses the

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length of the distal region of the guidewire core to be about 20 to 50 cm (column 6 line 12).

7. For claims 1, 2, 7-9, 12-14, 17-19, 24, 25, 30, 33-35, 38-40, and 48, Palermo et al discloses the claimed invention except for a single coil comprising a plurality of wire strands helically wrapped parallel to one another and disposed on tapered distal region of the core. Ferrera et al teaches a device configured for intravascular insertion comprising: a single coil 140 comprising a plurality of wire strands 142, as best seen in Figures 27 and 28, helically wrapped parallel to one another and disposed on at least a distal tapered portion of a guidewire core. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Palermo et al, with the helical microcoil with a plurality of strands taught by Ferrera et al for the purpose of configuring the distal tip of a guidewire for use in advanced surgical interventions requiring use of intravascular devices.

8.

9. Claims 15, 20, 21, 36, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo et al in view Ferrera et al and in further view of Fleischhacker et al (5165421). For claims 15 and 36, Palermo et al discloses the claimed guidewire except for the guidewire comprising 3 to 24 wire strands.

Fleischhacker et al teaches the use of a plurality of multifilar helically wound coil wires to comprise the guidewire (column 3 line 37) as seen in Figure 2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Palermo et al, with Fleischhacker et al for the

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purpose of structuring the guidewire in such a manner to control flexibility and torqueability by increasing or decreasing the number of wire strands.

10. For claims 20 and 41, Palermo et al discloses the claimed guidewire except for the plurality of helically disposed wire strands forming a tubular structure and wherein a portion of the distally tapered region is disposed within the tubular structure.

Fleischhacker et al teaches the use of a plurality of multifilar helically wound coil wires to comprise a tubular structure and disposing within the distally tapered guidewire region (column 6 line 58) as seen in Figures 9 and 10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Palermo et al, with Fleischhacker et al for the purpose of structuring the guidewire in such a manner to control the flexibility of the distal region.

11. For claims 21 and 42, Palermo et al discloses the claimed guidewire except for the angle between the wire strands and central longitudinal axis within the range of 10 to 45 degrees. Ferrera et al shows the angle between the wire strands and central longitudinal axis within the range of 10 to 45 degrees as seen in Figure 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Palermo et al, with Ferrera et al for the purpose of structuring the guidewire in such a manner to control the flexibility of the distal region.

Response to Arguments

12. Applicant's arguments with respect to claims 1,2,7-9,12-15,17-20,24,25,30,33-36,38-41 and 48 have been considered but are moot in view of the new ground(s) of rejection. Applicant argued (a) Palermo et al does not teach or suggest a guidewire

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comprising a single coil comprising a plurality of wire strands helically disposed parallel to one another and (b) Palermo et al in view of Fleischhacker et al does not teach or suggest a guidewire in which the angle between the wire strands and central longitudinal axis is from 10 to 45 degrees. With regards to argument (a), Palermo et al in view of Ferrera et al teaches and suggests a guidewire comprising a single coil comprising a plurality of wire strands helically disposed parallel to one another for the purpose of configuring the distal tip of a guidewire for use in advanced surgical interventions requiring use of intravascular devices. And with regards to argument (b), Palermo et al in view of Ferrera et al and in further view of Fleischhacker et al teaches and suggests a guidewire in which the angle between the wire strands and central longitudinal axis is from 10 to 45 degrees for the purpose of structuring the guidewire in such a manner to control the flexibility of the distal region.

13. The examiner notes previously withdrawn and presently amended claims 45, 46, and 49 are drawn to non-elected species and thus were not examined on the merits.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH


MICHAEL D. MCHEMERY
PATENT EXAMINER
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